

### **REMARKS**

Claims 1 and 3-13 were pending in the present application. Claims 1, 3, 4, 6-10, 12 and 13 were rejected. Claims 1, 5, 6 and 9 are herein amended. Claims 10-13 are herein cancelled without prejudice. No new matter has been entered. Applicants thank the Examiner for the courtesies extended in the telephone interviews of January 27, 2009, March 18, 2009 and March 19, 2009. Applicants' Statement of the Substance of the Interview is incorporated herein.

### **Applicants' Response to Claim Objections**

Claim 1 is objected to. The Office Action recommends that that "...cytoplasmic polyhedrosis is..." should be amended to recite "cytoplasmic polyhedrosis virus is...". Applicants herein adopt the Office Action's suggestions. Please see amended claim 1.

### **Unity**

The Office Action maintains that Group I (Claims 1, 3, 4, 6-10, 12 and 13), and Group II (claim 5 and 11) do not recite a shared technical feature which is a contribution over the prior art. In response, Applicants respectfully submit that Groups I and II do in fact recite a shared technical feature which is a contribution over the prior art. This shared technical feature is discussed in detail in the discussion of the §§102/103 rejection.

**Information Disclosure Statement**

Applicants herewith submit as an Information Disclosure Statement a copy of Mori et al. (1993), which is referred to on pages 14 and 17 of the application. Mori et al. discusses the nucleic acid sequence which encodes the polyhedral protein of strain H of *Bombyx mori* cytoplasmic polyhedrosis virus.

**Applicants' Response to Claim Rejections under 35 U.S.C. §112**

**Claims 1, 3, 4 and 10 were rejected under 35 U.S.C. §112, second paragraph, being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

It is the position of the Office Action that the reference sequence which the amino acid numbering in the claims refers to is unclear. The Office Action correctly notes that the amino acid numbering refers to a specific sequence. The Office Action suggests that the claims be amended to recite a sequence identifier such as "SEQ ID NO."

In response, Applicants herewith submit a sequence listing containing the nucleic acid and amino acid sequences of the capsid protein VP3 of strain H of *B. mori* CPV, which are identical to the nucleic acid and amino acid sequences of Figure 1 of Ikeda et al. Additionally, Applicants herein amend the specification in order to incorporate by reference the nucleic acid and amino acid sequences of Figure 1 of Ikeda et al., which was referred to in the "Background Art" section of the specification. These sequences are also registered in the GenBank database, as accession number AB041008. Finally, Applicants herein amend the claims in order to recite

the sequence listing identifier (SEQ ID NO: 2) corresponding to the amino acid sequence of capsid protein VP3 of strain H of *B. mori*. Applicants thank the Examiner for his assistance with respect to this matter. No new matter has been added. Favorable reconsideration is respectfully requested.

**Claims 1, 3, 4, 6-10, 12 and 13 were rejected under 35 U.S.C. §112, first paragraph, being as failing to comply with the written description requirement.**

With respect to claim 1, the Office Action states that “In view of the grammatically indefinite article “a” in the phrase “a” region from the 41st amino acid residue to the 79th residue,” the phrase has been broadly, but reasonably interpreted as any two contiguous amino acid sequence of a *B. mori* CPV strain H VP3 protein.” In order to obtain clarification of this statement, Applicants’ representative contacted the Examiner. The Examiner explained that he interprets the claim such that the restricted region could be *a part* of the sequence from the 41st to 79th amino acids. In other words, the Examiner interprets the claims such that the “restricted region” could be, for example two amino acids (such as the 41st and 42nd amino acids) or the shorted sequence (such as the 41st to 58th amino acids). Applicants’ representative explained that the Applicant wishes the claim the entire sequence from the 41st to 79th amino acids. Accordingly, the Examiner recommend amending the claims to recite that the restricted region consists of the 41st to 79th amino acid residues of the *B. mori* CPV strain H VP3 protein. Applicants herein amend the claims to adopt the Examiner’s suggestion. Please see amended claims 1, 5, 6 and 9.

Next, Applicants discuss the comments on pages 6 and 7 of the Office Action. The Office Action states that “other than the interaction between BmCPV strain H polyhedron and VP3, there is no way to predict interaction of any VP3 protein of any strain of *Bombyx mori* CPV with any other strain of *B. mori* CPV polyhedron to achieve a protein complex as encompassed by the claims.” In response, Applicants herein amend the claims to recite that the polyhedral protein is the polyhedral protein of strain H of *Bombyx mori* CPV, that the polyhedral protein has strain H of *Bombyx mori* CPV encapsulated therein, and that the VP3 protein is the VP3 protein of strain H of *Bombyx mori* CPV. Thus, Applicants respectfully submit that the pending claims fully comply with the written description requirement. Favorable reconsideration is respectfully requested.

**Claims 1, 3, 4, 6-10, 12 and 13 were rejected under 35 U.S.C. §112, first paragraph, being as failing to comply with the enablement requirement.**

It is the position of the Office Action that the specification, while being enabling for a protein complex of a *Bombyx mori* CPV strain H polyhedral protein having an encapsulated *Bombyx mori* CPV strain H and a target protein fused to the C-terminus of amino acids 41 to 79 of *Bombyx mori* CPV strain H VP3 protein, the specification does not reasonably provide enablement for all protein complexes as broadly encompassed by the claims.

Apart from the points discussed elsewhere regarding the interpretation of the “restricted region” and the direct or indirect fusion of the “restricted region” to the target protein, it appears that the Office Action questions whether the specification provides sufficient enablement for

protein complex having other polyhedral proteins than the polyhedral protein used in the Examples. As noted above, Applicants herein amend the claims to recite that the polyhedral protein is the polyhedral protein of strain H of *Bombyx mori* CPV, that the polyhedral protein has strain H of *Bombyx mori* CPV encapsulated therein, and that the VP3 protein is the VP3 protein of strain H of *Bombyx mori* CPV. Thus, Applicants respectfully submit that the pending claims fully comply with the enablement requirement. Favorable reconsideration is respectfully requested.

**Applicants' Response to Claim Rejections under 35 U.S.C. §§102/103**

**Claims 1, 3, 4, 9, 10 and 13 were rejected under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under §103(a) as being unpatentable over Ohta et al. (WO 02/36785.**

It is the position of the Office Action that Ohta discloses the invention as claimed. Ohta is directed at a cytoplasmic polyhedrosis virus polyhedron protein complex. Ohta discloses a target protein fused to a complete VP3 protein. In particular, the Office Action states that “there is no claim limitation that requires that target protein be heterologous to the restricted region and thus the “target protein” can be broadly but reasonably interpreted to be part of the VP3 protein itself, e.g., amino acids 1-40 or 80-1057.” Ohta discloses the following:

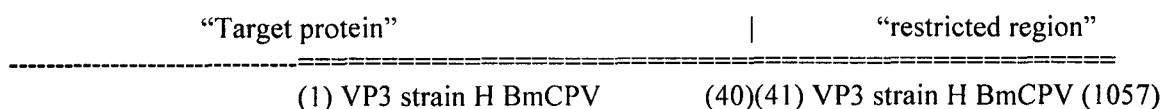
“Target protein”

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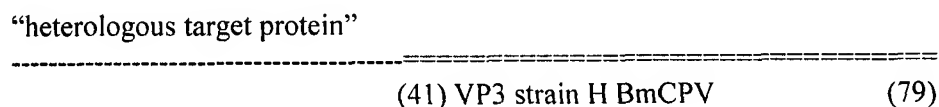
(1) VP3 strain H BmCPV

(1057)

However, the Office Action broadly interprets Ohta such that it discloses the following, where the “target protein” is comprised of part of the actual target protein and a portion of the VP3 protein itself:



In order to clarify the claimed subject matter, Applicants herein amend the claims to recite (i) that the target protein is heterologous with respect to the VP3 protein, and (ii) that the target protein is directly fused to the restricted region of the VP3 protein. Ohta does not disclose the following configuration:



Therefore, Ohta cannot disclose the subject matter of the independent claims—direct fusion of the heterologous target protein to the restricted region. As such, Applicants respectfully submit that Ohta does not disclose or suggest the embodiments as claimed. Favorable reconsideration is respectfully requested.

**Applicants' Response to Claim Rejections under 35 U.S.C. §103**

**Claims 6-8 and 12 were rejected under 35 U.S.C. §103(a) as obvious over Ohta in view of Hosokawa et al. (Materials Research Society, Symposium C, Bio-Inspired Nanoscale Hybrid Systems, December 2002, Abstract C3.5) and Ito et al (Appl. Physics Lett. 78: 2566-2568, 2001).**

It is the position of the Office Action that Ohta discloses the invention as claimed, with the exception of teaching the biosensor. The Office Action relies on Hosokawa and Ito to provide this teaching.

In response, Applicants respectfully submit that the disclosures of Hosokawa and Ito do not remedy the deficiencies of Ohta discussed above. Therefore, for similar reasons as discussed above with respect to claims 1 and 9, Applicants respectfully submit that claims 6-8 are patentable over Ohta, Hosokawa and Ito. Favorable reconsideration is respectfully requested.

**Applicants' Response to Double Patenting Rejections**

**Claims 1, 3, 4, 9, 10 and 13 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 7,432,347 ("the '347 patent").**

**Claims 6-8 and 12 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of the '347 patent, in view of Hosokawa and Ito.**

In response, Applicants respectfully submit that the claims of the pending application are patentably distinct over claims 1-6 of the '347 patent, for the reasons discussed above. Specifically, for reasons similar to those discussed above, Applicants respectfully submit that Ohta discloses a target protein fused to a complete VP3 protein, and does not disclose a heterologous target protein directly fused to a restricted region of VP3 from the 41st to 79th residues. As such, Applicants respectfully submit that the pending claims are patentably distinct over claims 1-6 of the '347 patent. Favorable reconsideration is respectfully requested.

For at least the foregoing reasons, the claimed invention distinguishes over the cited art and defines patentable subject matter. Favorable reconsideration is earnestly solicited.

Should the Examiner deem that any further action by applicants would be desirable to place the application in condition for allowance, the Examiner is encouraged to telephone applicants' undersigned attorney.

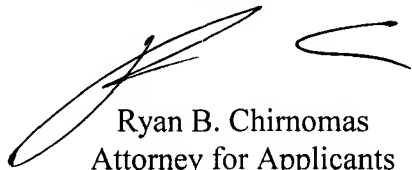


Application No.: 10/541,752  
Art Unit: 1656

Amendment  
Attorney Docket No.: 052777

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,  
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Enclosures: Sequence listing (computer readable format)  
Sequence listing (paper copy)  
Submission of sequence listing  
Information Disclosure Statement citing Mori *et al.*  
Mori *et al.*